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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,814	09/21/2007	Eduardo Marban	001107.00623	5612
22907 7590 03/22/2011 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051			EXAMINER KELLY, ROBERT M	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 03/22/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/593,814

Applicant(s)

MARBAN ET AL.

Examiner

ROBERT M. KELLY

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 85-97 is/are pending in the application.
- 4a) Of the above claim(s) 85,87-93 and 95-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 86 and 94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/15/10</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment and response of 1/18/11 are entered.

Claim 98 and 99 are cancelled.

Claims 85-97 remain pending.

### **Claim Status, Cancelled Claims**

In light of the cancellation of Claims 98-99, all rejections and/or objections to such claims are rendered moot, and thus, are withdrawn.

### **Election/Restrictions**

Applicant's election of Group XXVI, and the species of fibroblasts in the reply filed on 2/9/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 85, 87-93, 95-97 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/9/10.

Claims 86 and 94 are presently considered with respect to the elected species of fibroblasts.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant requested explanation why the rejection to U.S. Patent No. 6,124,620 was withdrawn. To wit, Applicant noted that the Examiner noted that 6,124,620 was to another inventor, while Applicant's argument was put to 6,214,620. The Examiner withdrew the rejection to 6,124,620 because it was to another and hence no further consideration for double patenting was required. However, no rejection to 6,214,620 was provided as the specification does not provide description for fibroblasts, and therefore, no further consideration was required to provide another ODP rejection at this time.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the cancellation of Claims 98-99, the claims no longer are drawn to specifically encompass the generic embodiments, and therefore, the rejections of Claims 86 and 94 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for comprising new matter, are withdrawn.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 86 and 94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,317,950 to Lee and the general knowledge in the Art, as demonstrated by U.S. Patent No. 4,927,843 to Teitz and U.S. Patent No. 5,856,185 to Gruber, et al.

Lee claims cardiac stimulation systems (Claim 1), which comprise fibroblasts (Claim 20), adapted to express connexin (Claim 21). The specification teaches that one construct to express the connexin is expressed off a lenti-virus promoter (Section entitled "Constructs for Connexin Nucleic Acids, paragraph 3). Further Lee teaches that the constructs can be expressed off a vector of choice, depending on whether integration or episomal location is wanted (e.g., Id.). However, Lee does not teach the specific use of lentiviral vectors.

Teitz teaches fibroblast cells which are infected with EIAV, one lentivirus (Section "D." Subsection "a. Effect of drugs against EIAV"). Gruber teaches that fibroblasts can be transformed with HIV (e.g., Section Labelled "C. Extracorporeal Treatment of Human, Chimpanzee and Macaque Cells to Induce Expression of Vector Encoded Proteins"). These examples demonstrate that it is known that to utilize lentivirus to infect fibroblasts. In fact, it is well known that Lentiviruses are especially good at transforming non-dividing cells as well as dividing cells, and hence, it should be good at transforming any fibroblast.

Moreover, the specific properties of an obvious composition are not found patentable unless the finding is unexpected (i.e., the Art specifically did not believe it would occur) or surprising (i.e., so far out of the understanding of the Artisan, that it just would not be believed to occur).

Hence, at the time of invention, it would have been obvious to make the invention. The Artisan would do so to transform the fibroblasts of Lee, and would have a reasonable expectation of success, as the elements are utilized for their art-recognized purposes.

**Response to Argument - Obviousness, Lee and the Knowledge of the Artisan, as  
articulated by Teitz and Gruber**

Applicant's argument of 1/18/11 has been fully considered but is not found persuasive.

Applicant argues that the rejection did not clearly set forth why would combine the teachings of the Art, and that therefore, the rejection does not meet the requirements set out in KSR v. Teleflex. Specifically, it appears that Applicant is arguing that (i) there is no reason to combine the teachings, and (ii) the Examiner did not state each step and how it is therefore obvious. (pp. 4-5, paragraphs bridging).

Such is not persuasive. The claims themselves are a method which one step: administering to cells (examined for fibroblasts as a species and Claim 94, which depends from Claim 86), a lentivirus encoding a connexin. The steps are very simple. The Examiner has shown reason to transform a fibroblast with a gene encoding a connexin (from Lee's claims), and has further shown that the Artisan understood lentiviruses may be used to transform fibroblasts. Therefore, from this, the Artisan, having the skill and knowledge of one of skill in the Art, would find the invention of transforming a fibroblast with a lentivirus to express a connexin transgene obvious. The Artisan would be motivated to do so to express the connexin as in Lee's claims. And the Artisan would find it reasonably predictable because the Art is utilized for Art-recognized purposes, not anything which was not reasonably predictable.

Applicant argues the Examiner's comment about what they term to be "incredible" in the OA of 1/18/11. (p. 5, paragraph 1), and declines to put forth a reason for unexpected results.

Such is disagreed with, but to assuage Applicant's arguments, the Examiner has removed the paragraph. Such paragraph was merely to inform Applicant of a way to attempt to overcome the rejection. If Applicant disagrees with what is unexpected or surprising, the Examiner really has no interest in arguing such on the record, as it is not ripe at this time to discuss it.

### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ROBERT M. KELLY** whose telephone number is (571)272-0729. The examiner can normally be reached on **M-F, 9:00am-5:00pm**.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/  
Primary Examiner, Art Unit 1633